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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,305	04/08/2004	William Andrew Wilson	P06296US02 - PHI 1443	7443
27142	7590	11/03/2005	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/820,305

Applicant(s)

WILSON ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 06/20/05 in reply to the Office action of 03/17/05 and the supplemental amendment of 08/08/05 have been entered. Claim 2 is amended. Claims 11-34 are added. Therefore, claims 1-34 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn.

### ***New Matter***

The amendment filed 06/20/05 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the material inserted into the original specification at page 75, the last sentence of 1<sup>st</sup> paragraph, stating, "Unauthorized seed multiplication prohibited. U.S. Protected Variety ". Nowhere in the originally filed disclosure provide basis for such introduced material.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

At claim 14, it is suggested that "wherein seed is allowed to form" be replaced with ---and harvesting the resultant seed---, for proper method steps.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup>***

Claims 11-12, 23, 25-28, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: repeating steps (c) and (d) for at least three or more times in order to produce progeny plants having the desired trait and comprise at least 95% of the alleles of inbred line PH8CW.

Claim 12 is indefinite because it is unclear if a plant having the desired trait and comprises at least 95% of the alleles of inbred line PH8CW is produced from the method of claim 11, since the method of claim 11 lacks essential method steps.

Claims 23-28 improperly depend from claim 13. The claims do not incorporate all elements of the parent claim. The plant of parent claim 13, PH8CW, does not contain a single locus conversion or any of the locus conferring traits as listed in claims 26-28. For example, claims 26-27 recite gene conferring male sterility. However, the parent plant is male fertile. See pages 22 of the specification (line 38, where the plant is characterized as having pollen shed rated as 5.7 (on a scale from zero being male sterile to 9 being heavy pollen shed). The plant of parent claim 13, PH8CW, does not contain a transgene, allele or locus. Therefore, claims 23- 28 do not incorporate all elements of the claim from which it depends.

Claim 32 is indefinite in the recitation of "using" without any active method steps. Dependent claims 33 and 34 are included in the rejection.

***Written Description***

Claims 1-12, 15-19, 21-26, and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 03/17/05. Applicant's arguments filed 06/20/05 have been considered but are not deemed persuasive.

Applicant argues that the claimed invention have been described specification by actual reduction to practice of F1 hybrid seed/plants produced from inbred maize line PH8CW and by description of common identifying structural feature which is the deposited seed of inbred PH8CW, as well as by description of SSR marker profiles as shown in Table 4 of the specification (response, p. 7).

These arguments are not persuasive because the specification does not provide a representative number of seed/plant hybrids of the genus claimed. Table 3 of the specification discloses a few F1 hybrids of PH8CW described by some agronomic traits such as yield, moisture, test weight and late season health, to compare the hybrid performance ability or hybrid combining ability of the inbred maize line PH8CW with other hybrids. Such hybrid performance comparison data cannot be extended to describe any other PH8CW hybrid plant that does not have both of the same parents, and are not representative of *all* hybrids produced using maize line PH8CW as only one

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parent and using a multitude of genetically and morphologically uncharacterized and unrelated maize plants as a second parent.

Applicant argues that the claimed hybrids are in accordance with Eli Lilly standard because that cells and/or chromosomes of inbred line PH8CW provide structural characteristics sufficient to distinguish all PH8CW hybrids from hybrids that do not made with PH8CW. Applicant also relies upon the SSR profiles of Table 4 to support written description of the claimed plants/seed (response, page 7-8).

Examiner maintains that the claimed plants/seed hybrids and the plants/seed of the deposited line do not share common essential features because the essential feature of the hybrids are determined by the interaction of the genetic materials from both parents involved in the breeding. Hybrids produced by crossing PH8CW with other, distinct inbred maize plants would, of course, produce plants that do not express the same traits as PH8CW. In addition, while the claimed hybrids will inherit the SSR marker profile of PH8CW, they will not inherit the same genetic markers from the other parents (non-PH8CW parents involved in the breeding) because they have different parents having different markers. The SSR marker profiles of other parents are not described. In addition, the specification does not describe the traits that are associated with the SSR loci of Table 4. The SSR are named, but the written descriptions of the sequence of each of the SSR markers are not provided. Without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

Applicant asserts that the deposited seed of the inbred PH8CW contributes to the written description of the plants and seed of claims 1-10 and 11-12. Applicant cites *Enzo Biochem. Inc.*, 323 F3d at 965, 63 U.S.P.Q. 2d at 1613. Applicant also reiterates that the claimed F1 hybrid will inherit the SSR marker profile described on Table 4.

These arguments are not persuasive. In the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material, it is noted that in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. As in *Enzo*, here the deposited inbred seed does not correspond exactly to the claimed seed or plant comprising at least one set of the chromosomes of maize inbred PH8CW, including F1 hybrid seed/plant. The functions of the claimed hybrid plants/seed have not been correlated to the set of chromosomes originating from the deposited PH8CW seed. The function of the plant grown from a PH8CW seed is correlated with the structure of its entire genome. The functions of the claimed hybrid plants grown from the claimed hybrid seeds are correlated with the structures of their entire genomes, not just the set of chromosomes inherited from PH8CW. Furthermore, half of the alleles of the hybrid are inherited from the other parent (a non-PH8CW), and are not described by the deposited PH8CW seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited PH8CW seed. Therefore, the deposited

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seed of the inbred PH8CW does not provide written description for F1 hybrids produced from the inbred PH8CW.

Applicant further asserts that the genus of F1 hybrid seed and plants encompassed by claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH8CW, and that each F1 hybrid produced from PH8CW will comprise this unique set of chromosome of PH8CW. Applicant also asserts that this unique set of chromosomes described in the SSR profile of Table 4 of the specification is sufficient to describe the genus of claimed hybrids. Applicant further asserts that the genetic/morphological characteristics of all F1 hybrid seed/plants, produced from crossing inbred PH8CW with any other maize line, are not expected to vary from inbred PH8CW (response, paragraph bridging pages 8 and 9, and the last two full paragraphs of page 9).

Examiner agrees with Applicant that a hybrid produced from inbred will receive one set of chromosomes from that inbred, regardless of whether the inbred is used as male or female parent of the F1 hybrid. However, where the breeding involves unknown various non-PH8CW parents, all F1 hybrids will not receive the same set of chromosomes from each of the parents involved in the breeding. For example, if PH8CW carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the



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inheritance of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is the interaction between the two sets of alleles from both parents that determine the morphological and genetic characteristics of the F1 hybrid. One cannot predict which set of alleles a hybrid will receive from its parent. Applicant has provided no scientific evidence to support the conclusion that the genetic/morphological characteristics of all F1 hybrid seed/plants, produced from crossing inbred PH8CW with any other maize line, are not expected to vary from inbred PH8CW. Applicant also has provided no evidence that these F1 hybrids are reproducible.

Applicant alleges that the Examiner is setting a new standard of written description that exceeds that required by law (page 10, 1<sup>st</sup> full paragraph). However, Applicant points to no specific requirement set forth in the last Office action that exceeds the written description requirement as set forth in the MPEP 2163 or related case law.

At the paragraph bridging pages 9 and 10, and the last two full paragraphs of page 10, Applicant repeats the arguments that the deposit of the seed of inbred PH8CW is sufficient to describe F1 hybrid plants/seed and that the unique set of chromosomes from inbred PH8CW distinguish them from non-PH8CW hybrids. Applicant continues to cite Enzo. Biochem and Eli Lilly.

However, again, hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH8CW does not provide any description for the hybrids. The claimed hybrids will not have the similar morphological and physiological characteristics as PH8CW. PH8CW plants can be crossed with any other inbred maize plant to produce the claimed hybrids. The claimed hybrids then will express a combination of set of alleles that are different from each other, and which are also different from those expressed by PH8CW. That all hybrids will inherit two sets of alleles from PH8CW does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids.

At the paragraph bridging pages 10 and 11, Applicant asserts that genetic composition of the pericarp tissue of the F1 seed is an identifying structural characterizes for F1 seed and plants produced from said seed, when PH8CW is the maternal parent.

Examiner respectfully disagrees for the following reasons: Firstly, the rejected claims are not drawn to pericarp tissues from the deposited maize seed. The claims are directed to F1 hybrid seed and plants of PH8CW. Secondly, even if one assumes that F1 hybrid seed receives an intact cell from a maternal inbred parent PH8CW, the morphological/physiological characteristics of the F1 seed is not determined by the genetic material of the intact cell only. Thirdly, since maize seed is made up of various types of tissues with different compositions, it is the complete structure and complete

genetic materials of these various tissues that determines the morphological characteristics of the seed. In addition, the rejected claims do not recite inbred PH8CW is used as the maternal parent for all hybrids. This rejection also applies to claim 7-10 as discussed in the last Office action 03/09/05. Claims 7 and 9 encompass F1 hybrid seed, while claims 8 and 10 encompass F1 hybrid plants or part thereof produced from the F1 hybrid seed.

Applicant further argues that the specification describes how to produce F1 hybrid from inbred maize line PH8CW, and that a genus of F1 hybrid may be produced because Applicant provided PH8CW.

Examiner responds that the claims drawn to a method producing F1 hybrids from the inbred PH8CW are not rejected. Applicant, however, has not described the genus of F1 hybrids produced by said methods for the reasons discussed above. One skilled in the art would not recognize from the disclosure that Applicant was in possession of F1 maize hybrids as encompassed by the claims.

On page 12 of the response, Applicant summarizes his arguments as follows: a) the cells/chromosomes of inbred of PH8CW provide identifying structural feature common to all members of the genus of F1 hybrids; b) each hybrid of PH8CW receives a complete set of chromosomes of PH8CW, and a description of the set of chromosomes is disclosed in Table 4 of the specification; c) SSR profile of PH8CW is obtainable from the deposited seed of PH8CW and that methods of using SSR markers are known in the art; d) F1 hybrid seed and plants produced from said seed will contain

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an intact cell from inbred PH8CW. Applicant asserts that these descriptions are sufficient to provide distinguishing characteristics for the F1 hybrid plants/seed.

However, examiner maintains that hybrids that do not share both of the same parents will not have the same traits and the fact that they share one set of chromosomes from PH8CW does not provide any information concerning the morphological and physiological characteristics that will be expressed by the hybrids. The morphological/genetic characteristics of the hybrids are not determined by one set of chromosomes from parent PH8CW, but rather the interaction between the genetic materials from both parents. Regarding the SSR markers, the specification does not describe the traits that are associated with the SSR loci of Table 4 and the written descriptions of the sequence of each of the SSR marker are not provided. Without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant. In addition, the specification does not describe the SSR marker profiles of other non-PH8CW parents involved in the breeding.

Claims 11-12, 19, 21 are further rejected because the SSR loci listed in Table 2 are not structurally or functionally described. The SSR are described by name only, and not by trait or by structure such as sequence.

New claims 15-25, drawn to hybrid seed/plants of the inbred PH8CW, are included in the rejection because the specification fails to describe a representative number of hybrids of the genus claimed, as discussed in the last Office action. The specification only compares hybrid performance data of three hybrids containing

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PH8CW with other hybrids. Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred PH8CW with any and all other inbred or hybrid maize plants.

Claims 23-25, drawn to a maize plant of inbred PH8CW further defined as having a genome with single locus conversion, are rejected because the claims do not place any limitation on the trait conferred or affected by the single locus conversion. The claims also broadly encompass single loci that have not been discovered or isolated.

Claims 26-27 are rejected. The specification indicates a single locus conversion of PH8CW occurs when DNA sequences are introduced into the plant by traditional breeding techniques such as backcrossing (page 30, 1<sup>st</sup> full paragraph). However, the specification provides no description of any plant produced by classical breeding methods such as backcrossing or recurrent selection. No other maize plant ("donor parent") exhibiting a single desired trait for use in backcross breeding has actually been disclosed and described, and no resulting progeny from such a cross has actually been disclosed or described. Furthermore, the individual genes conferring the desired traits have not been characterized, and the genes for several of the contemplated traits, i.e. "improved nutritional quality" and "yield stability" as claimed in claim 26 have not been isolated. In fact, the genes conferring such traits are thought to be quantitative in nature, i.e. governed by multiple genes, often occurring on different chromosomes, which additively contribute to the desired effect.

Claims 29-32 are included in the rejection because the claims read on a method for crossing PH8CW with a multitude of non-exemplified breeding partners which have

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not been characterized either morphologically or genetically. Only PH8CW has been morphologically described in the specification, as possessing a particular combination of traits as set forth in Table 1. PH8CW has not been described with regard to its genetic complement, i.e. the particular collection of genes that confer all of the traits it exhibits.

Claims 33-34 are included in the rejection because the claims require the use of a multitude of non-exemplified molecular markers. The instant specification does not characterize or described even one maize molecular marker, with regard to sequence, length or source. Thus, the claim reads on a method of using inadequately described products, rendering the method of using such products similarly inadequately described.

Therefore, for all the reasons discussed above and in the last Office action, the claimed invention lacks adequate written description. The rejection is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 24-25 of U.S. Patent No.

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6, 784, 349. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the patent are directed to plants and parts thereof of PH8CW and methods of introducing a desired trait into said PH8CW plants by breeding methods and plants produced by said methods.

***Remarks***

Claims 1-12 and 15-34 are deemed free of the prior art, given that the prior art does not teach or fairly suggest inbred maize PH8CW or a hybrid maize seed/plant produced from the inbred, as stated in the last Office action.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/28/05

Mai

MEDINA A. IBRAHIM  
PATENT EXAMINER

